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| PPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|------|------------|----------------------|---------------------|-----------------|
| 10/642,642 | (| 08/19/2003 | Dov Zipori | 85189-4900 | 3766 |
| 28765 | 7590 | 11/21/2005 | | EXAMINER | |
| WINSTON | | | JALLA, SANJOO | | |
| 1700 K STREET, N.W. WASHINGTON, DC 20006 | | | | ART UNIT | PAPER NUMBER |
| | | | | 1644 | |

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|--|--|---|
| | 10/642,642 | ZIPORI ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Sanjoo Shree Jalla | 1644 |
| The MAILING DATE of this communication app | <u> </u> | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). |
| Status | | |
| Responsive to communication(s) filed on 19 A This action is FINAL . 2b) ☐ This Since this application is in condition for alloware closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | |
| Disposition of Claims | , | |
| 4) Claim(s) 1-26 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-26 are subject to restriction and/or or other contents. | wn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11. | epted or b) objected to by the drawing(s) be held in abeyance. Se tion is required if the drawing(s) is ob | e 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea * See the attached detailed Office action for a list | es have been received. Is have been received in Applicat Frity documents have been receiv In (PCT Rule 17.2(a)). | ion No ed in this National Stage |
| Attachment(s) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summan Paper No(s)/Mail D | |
| 2) Notice of Draitsperson's Patent Drawing Review (F10-946) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5. The second | Patent Application (PTO-152) |

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-11, 13-15 and 17, drawn to an isolated polynucleotide comprising a transcript of a T cell receptor (TCR) gene, an expression vector and host cell, classified in Class 435, subclass 6.
- II. Claims 1 and 12, drawn to an antisense polynucleotide, classified in Class 435, subclass 6.
- III. Claims 16, 18 and 19 drawn to a polypeptide encoded by a polynucleotide and a synthetic peptide, classified in Class 530, subclass 300+.
- IV. Claims 20 and 21, drawn to an antibody raised against a peptide, classified in Class 424, subclass 133.1 and class 530, subclass 387.1.
- V. Claims 22 and 23, drawn to a method for inducing mesenchymal cell growth, classified in Class 424, subclass 173.1.
- VI. Claims 24 and 25 drawn to a method for suppressing mesenchymal cell growth, classified in Class 424, subclass 173.1.
- VII. Claim 26, drawn to a method of marking mesenchymal cells comprising an antibody, classified in Class 424, subclass 139.1.
- 2. Groups I-IV are unrelated products. Invention I is drawn to a polynucleotide while invention II is drawn to an antisense polynucleotide and invention III is drawn to a polypeptide. Further, invention IV is drawn to an antibody. These products are structurally different and have different uses (eg. hybridization assays using invention I, versus signal transduction using polypeptides and immunopurification or immunoassay using antibody and inhibition of gene function using antisense polypeptide). Therefore they are novel and unobvious in view of each other and are patentably distinct.
- 3. Groups V- VII are different methods. In the instant case the different inventions are drawn to methods comprising different

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method steps, different reagents, resulting in different end points. For example, the steps and reagents used and the endpoint of a method for inducing mesenchymal cell growth of group IV is distinct from the steps and reagents required for a method of suppressing mesenchymal cell growth of group V. Furthermore, the steps and reagents used are different in a method of group VI where mesenchymal cells are marked applying an antibody.

- 4. Groups I and V are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Polynucleotide can be used as a probe in DNA fingerprinting.
- 5. Groups II and VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, antisense Polynucleotide can be used in the development of antisense drugs.
- 6. Group IV and VII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, an antibody can be used in immunopurification or immunoassay.
- 7. Groups V-VII do not use the product of group III.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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Applicant is required to elect a polynucleotide sequence from any one of SEQ ID Nos: 1-37.

The species of polynucleotide SEQ ID Nos: 1-37, while related in that they are all polynucleotides, are still patentably distinct. The polynucleotides of SEQ ID Nos: 1-37 are structurally and functionally distinct, as demonstrated by their unique amino acid sequences.

- 9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant muct indicate which are readable upon the elected species. MPEP § 809.02(a).
- 11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the

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limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

- 14. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent See MPEP § 804.01. issues.
- 15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 16. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art because of their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a

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prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

- 17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sanjoo S Jalla whose telephone number is 571-272-4453. The examiner can normally be reached Monday through Friday from 8:30-5pm.
- 18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- 19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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G.R. EWOLDT, PH.D. PRIMARY EXAMINER